

Patient information leaflet

Synalar® gel

fluocinolone acetonide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Synalar gel is and what it is used for
2. What you need to know before you use Synalar gel
3. How to use Synalar gel
4. Possible side effects
5. How to store Synalar gel
6. Contents of the pack and other information

1. WHAT SYNALAR GEL IS AND WHAT IT IS USED FOR

Synalar gel contains fluocinolone acetonide which is a corticosteroid (also referred to as a steroid) and reduces inflammation.

It is used to treat certain inflammatory conditions such as seborrhea and psoriasis of the scalp and other hairy parts of the body. It may also be used to treat certain inflammatory conditions of the skin on other parts of the body.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Synalar gel is classed as a **strong** corticosteroid.

Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SYNALAR GEL

Do not use Synalar gel:

- If you are allergic to fluocinolone acetonide or any of the other ingredients of this medicine (listed in section 6).
- Where infection is the main cause of the skin problem.
- For acne.
- For nappy rash or itchiness around the genital area.
- If you have a skin condition called rosacea which is red rash, sometimes with spots and pustules, on the cheeks of the face.
- If you have a skin condition called perioral dermatitis which is a dry sore red rash around the mouth

- If it is for a child under the age of one.
 - If breast-feeding, do not apply to the breasts prior to nursing.
- Make sure your doctor knows if any of the above affects you.

Warnings and precautions

- Synalar gel should be kept away from the eyes.
- If using Synalar gel on the face or on children (over the age of 1 year), do not use for more than 5 days. Your doctor will tell you if your treatment should be longer than this.
- Waterproof dressings should not be used for children, or the face, and only in adults if your doctor tells you. The affected area should be thoroughly cleaned before putting on a waterproof dressing. Ask your doctor for instructions.
- Do not use more gel than the doctor tells you, especially if you are pregnant or breast-feeding.
- If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the gel without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.
- If too much gel is used for too long, you may develop stretch marks, thinning of the skin, or visible small veins.

Other medicines and Synalar gel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

If you go into hospital, let the medical staff know that you are using Synalar gel.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Synalar gel should not affect your ability to drive or use machinery.

Important information about some of the ingredients of Synalar gel

Some of the ingredients in your gel may cause a reaction, such as: Methyl and propyl parahydroxybenzoate [E218 and E216] – may cause local skin reactions (possibly delayed). Propylene glycol [E1520] – may cause skin irritation.

3. HOW TO USE SYNALAR GEL

Always use Synalar gel exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use the nozzle of the tube to apply your gel directly on to the affected part of the skin at the roots of the hair.

Unless your doctor tells you differently, a small amount of gel should be massaged into the affected area every night and every morning at roughly the same time.

Once the condition is under control you can reduce the treatment and apply the gel once or twice a week. Use the gel for as long as directed by your doctor (normally 5 days on the face and on children).

If you forget to use Synalar gel

If you forget to apply the gel at the correct time, do so as soon as you remember.

If accidentally swallowed

If you accidentally swallow the gel, contact your nearest doctor or hospital.

If you have any further questions on the use of this medicine ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines Synalar gel can cause side effects, although not everybody gets them. The following side effects have been reported but how often they occur is unknown:

- an allergic (itchy) reaction to the gel
- irritation where the gel has been applied
- a worsening of acne, rosacea and dermatitis around the mouth (see section 2)
- patches of pale skin (depigmentation)
- localised increased hair growth
- if too much gel is used for too long, you may develop stretch marks, thinning of the skin or visible small veins. In addition some of the steroid rubbed in to the skin may enter the blood stream. Effects such as roundness of the face, muscle wasting and fluid retention, as sometimes seen when steroids are given as tablets, may occur. The risk of these possible effects is higher in children. If this happens, your doctor may decide to stop treatment.
- Steroid withdrawal reaction: if used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after stopping treatment, with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

Do not be alarmed by this list of possible side effects. You may not have any of them.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SYNALAR GEL

Keep this medicine out of the sight and reach of children. It could harm them.

Store Synalar gel below 25°C. Keep the gel in the tube it came in.

Do not use this medicine after the expiry date which is stated on the tube and carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Synalar gel contains

The active substance is fluocinolone acetonide. Synalar gel contains 0.025% w/w fluocinolone acetonide.

The other ingredients are carboxypolymethylene, citric acid, disodium edetate, methyl parahydroxybenzoate [E218], propyl parahydroxybenzoate [E216], propylene glycol [E1520], industrial methylated spirit, purified water and triethanolamine.

What Synalar gel looks like and contents of the pack

Synalar gel comes in tubes of 30 and 60 grams.

Marketing authorisation holder:

Reig Jofre UK Ltd, Unit 9A Caddsdwn Business Support Centre, Caddsdwn Industrial Park,
Bideford, Devon EX39 3DX, UK

Manufacturer: Bioglan AB, PO Box 50310, S-202 13 Malmö, Sweden.

'Synalar' is a registered trademark.

This leaflet was last revised in January 2024